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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,160

11/16/2005

Lasse Petersen

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EXAMINER

OSTRUP, CLINTON T

ART UNIT

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3771

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/552,160	<b>Applicant(s)</b> PETERSEN ET AL.	
	<b>Examiner</b> CLINTON OSTRUP	<b>Art Unit</b> 3771	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 and 28-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 October 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/20/06</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 1-26 and 28-30 are pending in this application. Claim 27 has been cancelled as directed by applicant in the preliminary amendment filed October 11, 2005.

#### ***Specification***

2. The disclosure is objected to because of the following informalities: the first paragraph of the specification is missing text on lines 1-4.  
  
Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 2, 4-5, 7, 9, and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. The term "general" in claims 2, 5 and 7 is a relative term which renders the claim indefinite. The term "general wall thickness" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear what is meant by "general wall thickness" and therefore it is unclear what wall thicknesses are included or excluded by the claim.
6. The term "essentially" in claim 4 is a relative term which renders the claim indefinite. The term "essentially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the

art would not be reasonably apprised of the scope of the invention. It is unclear how “essentially elliptical, drop-shaped, annularly extending or a variety thereof” the outer contour of an inner circumference of a cuff must be to be included or excluded as claimed.

7. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 9 and 23 recite the broad recitation an outer jacket... partially encloses the outer faces of the rigid tubing, and the claims also recite that the outer jacket...completely encloses the outer faces of the rigid tubing, which is the narrower statement of the range/limitation.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. **Claim 28 is rejected under 35 U.S.C. 102(b) as being anticipated by Brain (4,241,956).**

Brain discloses a laryngeal mask (figures 10-12) comprising at least one airway tube (11) and a mask portion (10), which mask portion (10) comprises a top face (13) and a bottom face (opposite from top face), said bottom face comprising a lumen (14) that communicates with the tube (11) interior, and said top face (13) comprising a closed transition face, said mask portion (10) being at least on the bottom face in the periphery delimited by an inflatable cuff (18), wherein the cuff (18) of the mask portion comprises inflatable means 21 for abutment against a wall of a pharynx opposite a laryngeal opening for providing a tight connection of the mask portion and the laryngeal opening; and passages are formed between these abutment means and the top face of the mask portion. See: col. 8, line 28 – col. 10, line 42 and figures 10-12.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. **Claims 1-10 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collins (EP 1219316 A2) in view of Pagan (6,604,525).**

Regarding claim 1, Collins discloses a laryngeal mask (see figure) comprising an airway tube (1) having a lumen (hole in tube); and a mask portion (2), said mask portion (3) comprising an inflatable cuff (21); and an intermediary portion (20) forming a transition from said airway tube (1) to said inflatable cuff (21), wherein the airway tube (1) and the intermediary portion (20) are integrally molded, and the inflatable cuff (21) has a first peripheral edge integrally with said intermediary portion (where 25 forms the peripheral edge to where the cuff is attached) a second peripheral edge (where 26 forms the edge where the cuff is attached) connected to said intermediary portion by a joint (adhesive forming connection). Collins teaches all the limitations of instant claim 1 except the inflatable cuff with a first peripheral edge integrally molded with said intermediary portion. See: page 1, [0001]-[0012], figure and abstract.

Pagan teaches integrally forming a mount and a cuff member of a laryngeal mask. See: col. 1, line 35 - col. 3, line 47 and figures 1-9.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the laryngeal mask disclosed by Collins by integrally forming a cuff to a mount, as taught by Pagan to obtain a one piece, integrally formed laryngeal mask that eliminates the time consuming gluing of a cuff and the possibility of a faulty bonded cuff.

Regarding claims 2-8, Collins discloses that the cuff is a thin flexible plastic material and that by molding the tube and mount together enables the wall thickness or shape to be varied, if desired, at different points along the tube. Thus, modifications of

the tube thickness are clearly taught by the reference and the mere modification of a tube size is within the skill of those in the art.

Regarding claim 9, the combined references teach a rigid tubing (10) in extension of the airway tube which is completely or partially enclosed by an outer jacket (12) configured as an integral part of the airway tube. See: Pagan, figure 1.

Regarding claim 10, Collins discloses a groove in the airway tube and since the combined references teach the rigid tube as an integral part of the airway tube, it would have been obvious to extend the groove through the entire length of the tube, thus, including the rigid tube. See: Collins, page 1, [0006] and figure 1.

Regarding claim 12, Collins teaches an integrally formed mount and tube made by injection molding. See: Collins, page 2 [0013].

Regarding claim 13, Pagan teaches surface formations in the form of ribs, or the like, as epiglottis glides. See: col. 2, lines 62-65. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified shape of the epiglottis guides into more round bead like structures to perform the same function.

12. **Claims 11 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collins (EP 1219316 A2) in view of Pagan (6,604,525), as applied to claim 1 above and further in view of Brain (2003/0037790).**

The combined references teach all the limitations of claim 11 except the reinforcing ribs that are integral with the airway tube and axially parallel with the central axis of the airway tube.

Brain teaches a laryngeal mask with an airway tube that has reinforcing ribs that are integral with the airway tube and axially parallel with the central axis of the airway tube. See: page 10, [0156] and figures 10B, 10C, 10E, 37D, 48B, 48D, and 49B.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the airway way tube disclosed by the combined references by adding reinforcing ribs as taught by Brain to obtain an airway tube with a better fit to the anatomical airway than cylindrical tubes.

Regarding claims 14-15, Brain teaches a mask portion with two additional inflatable bellows on the top face of the mask. See: Brain, page 18, [0211]-0213] and figures 28-29.

Regarding claim 16, it is common knowledge in the art to apply a water soluble lubricant to an object prior to inserting it into a patient's orifice. Water soluble lubricants allows for easier, less intrusive insertion of objects into patient's orifices and it would have been obvious at the time the invention was made to one having ordinary skill in the art to apply a lubricant prior to a laryngeal mask prior to inserting it into a patient's airway.

Regarding claim 17, Brain teaches a reinforced transition face comprising reinforcing ribs. See: figures 10F, 10G, 48 D, and 49B.

13. **Claims 18-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collins (EP 1219316 A2) in view of Pagan (6,604,525), and further in view of Hicks et al., (GB 2367525 A).**



Regarding claim 18, the combined references teach a method of manufacturing a laryngeal mask with an airway tube having a lumen; and a mask portion, said mask portion comprising an inflatable cuff (9); and an intermediary portion forming a transition (8) from said airway tube (2) to said inflatable cuff (9), and teach that the mask portion and airway tube made by injection molding.

However, the combined references lack the injection molding process comprising injection molding of the airway tube, the intermediary portion and the cuff having an annularly extending opening between a second peripheral edge of said cuff and said intermediary portion integrally in a closed mould part in a first step, ejecting the airway tube, the intermediary portion and the cuff having the annularly extending opening from the mould in a second step, and providing a closed inflatable cuff by closing of the annularly extending opening by assembling the second peripheral edge with said intermediary portion by a joint.

Hicks teaches a method of injection molding a face mask in a two step method wherein the mask is formed in the first step and a cushion is formed in a second step. See: page 3, third full paragraph - the end of page 4; figures 1-5 and abstract.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have formed the mount and tube in one injection molding step as disclosed by Collins and then formed a cuff around the mount as disclosed by Pagan in a two step injection molding process as taught by Hicks to obtain a one piece laryngeal mask using a two step injection molding process.

Regarding claim 19, it appears that Pagan teaches the distance between the second peripheral edge and the intermediary position at the annularly extending opening as 1-8 mm, however, if the size is somewhat greater than 1-8 mm, mere modifications of sizes are design characteristics that are well within the skill of those having ordinary skill in the art.

Regarding claim 20, the Hicks reference teaches a method wherein a liquid polymer material is injected into a closed mould at a first pressure and a first temperature, wherein the mould comprises at least one core for providing the inner cavity in a tube (3) and mask portions (13), wherein the mould also comprises two first mould parts, an upper first mould part (5) and a lower first mould part (4), whose interfaces comprise a first interface (forming 13) that is situated in the area corresponding to a lower face of the mask and movable perpendicular to each other's interface; and wherein the mould also comprises two further second mould parts (forming 9).

However, Hicks does not specifically describe a second movement pattern that is perpendicular to the movement line of the first mould part; the lower first mould part is moved away from the upper mould part; the two second mould parts are moved away from each other by use of second movement pattern; the core is subsequently moved in the same direction as the lower first mould part; and the mask then being finished by ejection from the mould and closing of the annularly extending opening.

Due to the size and shape of a laryngeal tube, it would necessarily be formed by a different sized and shaped mold as compared to that of Hicks. However, Hicks was

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used to show that an injection mold process is capable of forming both a mask and a patient interface. Since, the combined references teach that a laryngeal airway tube, mount, and cuff can be formed by molding plastics, and Hicks teaches using injection molding to form a mask and a patient interface, the mere designing of a mold for the laryngeal mask is well within the skill of one in the art. Thus, the perpendicular movement and rough core surfaces, as claimed are merely obvious design characteristic of the two step molding process.

Regarding claim 22, the combined references teach a the periphery of the mask portion is formed by an upper and a lower periphery configured by a tongue/groove arrangement, also known as a male/female arrangement, that is subsequently assembled against each other, for providing an essentially closed peripheral cuff. See: Hicks figures 2-5.

Regarding claim 23, the combined references teach a method wherein rigid tubing is arranged in extension of the airway tubing to the effect that an outer jacket configured as an integral part of the airway completely or partially encloses the outer faces of the rigid tubing. See: Pagan figure 1.

Regarding claim 24, the combined references teach a method wherein the airway tube and the mask portion are molded around the rigid tubing. See: Collins, col. 1 [0005] and Pagan col. 3, lines 34-39 and figure 1.

Regarding claim 25, the combined references teach a method wherein the airway tube, the mask portion and the rigid tubing are manufactured from the same polymer material. See: Pagan col. 1, lines 38-48.

Regarding claim 26 the combined references teach a method wherein a tube is subsequently mounted on the peripheral cuff of the laryngeal mask, which tube is at the other end provided with a valve and pilot balloon. See: Collins, col. 2, [0011].

14. **Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brain (5,241,956) in view of Brain (2003/0037790).**

Brain '956 discloses all the limitations of claim 29 except the cuff of the mask portion having at least two inflatable lateral bellows that are arranged on the top face of the mask and symmetrical about a longitudinal axis of the cuff. See: figures 28 & 29.

Brain '790 teaches two inflatable lateral bellows that are arranged on the top face of the mask and symmetrical about a longitudinal axis of the cuff.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the laryngeal mask of Brain '956 by using the two inflatable lateral bellows, as taught by Brain '790 to obtain a laryngeal mask that provides a symmetrical cushioned support to the back wall of the patient's pharynx.

15. **Claim 30 as rejected under 35 U.S.C. 103(a) as being unpatentable over Collins (EP 1219316 A2) in view of Pagan (6,604,525), as applied to claim 1 above and further in view of Cook (6,422,239).**

The combined references teach all the limitations of claim 30, except the cuff with reinforced sections foremost on a top face of the cuff.

Cook teaches a laryngeal mask with a cuff that has reinforced sections on the top face of the cuff. See: col. 5, line 54 – col. 6, line 12 and figure 4.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the laryngeal mask disclosed by the combined references by using raised runners as taught by Cook to form a cuff that help guide the laryngeal mask and help prevent lateral movement once the tube laryngeal mask is positioned in the body.

***Conclusion***

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Brain (6,705,318); Brain (5,391,248); Brain (5,305,743) and Collins (2002/0078961) which teach laryngeal masks and Namey (2002/0020416) which teaches forming breathing masks using injection molding techniques.
17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.
18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/

Examiner, Art Unit 3771

/Justine R Yu/

Supervisory Patent Examiner, Art Unit 3771